

**EXHIBIT A
TO
SUR-REPLY OF VEN-A-CARE OF THE FLORIDA KEYS, INC.**

COMPARISON CHART OF VEN-A-CARE AND SUN/HAMILTON ALLEGATIONS

Sun/Hamilton Complaint filed 04/19/05 (Docket Entry # 57-2) ¹	Ven-A-Care Complaint filed 12/11/02 (Docket Entry # 8205-3)
<p>1. This is a qui tam action brought by LINNETTE SUN and GREG HAMILTON on behalf of the United States and various States to recover penalties and damages arising from fraudulent and illegal practices of Baxter Hemoglobin Therapeutics, a division of Defendant Baxter International, Inc. (hereinafter “Baxter”). Baxter makes a variety of specialized pharmaceutical, hematological, and infusion products, known in the industry as “biologics.” Government programs reimburse healthcare providers who purchase these products based upon the published or posted Average Wholesale Price (“AWP”). Manufacturers, such as Baxter, are to report an accurate Wholesale Acquisition Costs (“WAC”) to the database that calculates and publishes the AWP based upon the reported WAC, First DataBank, Inc. (“FDB”).</p>	<p>1. This is an action for damages, treble damages, restitution, civil penalties, pre-judgment interest, equitable relief and for attorneys’ fees and expenses of the Relator against the DEFENDANTS for violations of the False Claims Act as set out in Counts I through VI. The violations arise from DEFENDANTS’ actions which caused Medicare and the State Medicaid Programs to pay grossly inflated prices for DEFENDANTS’ prescription drugs. This Fourth Amended Complaint encompasses all those prescription drugs and biologicals with respect to which DEFENDANTS violated the False Claims Act during the relevant time period by any of the means described herein, including, but not limited to, the prescription drugs and biologicals identified herein unless otherwise included by the Relator in a separate action under the False Claims Act.</p>

¹ The amended complaints later filed by Relators Sun/Hamilton contain the same allegations.

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<p>2. It is known throughout the industry and known to Baxter that FDB calculates this mark-up. Baxter controlled the published AWP by misreporting the WAC. Baxter provides to the States, directly and through submission of reports to drug pricing publishing services, what purports to be genuine pricing data for its products. This information is typically identified as the “Wholesale Acquisition Cost” (“WAC”) and/or the “Average Wholesale Price” (“AWP”) of particular products. Baxter intends the WAC to be understood by the state Medicaid agencies as the average price paid by a wholesaler to a manufacturer for a given product. Baxter intends the AWP to be understood by the state Medicaid agencies and other payors as the average price charged by a drug wholesaler to its commercial customers for a given product.</p>	<p>63. First DataBank, Medical Economics and Medi-Span all report drug prices that include a representation of the drugs’ AWP.</p>
<p>3. The drug pricing publishing services in turn compile, publish and distribute compendia of such pricing information for each defendant’s products. The drug pricing publishing services purport not to investigate the accuracy of the information provided by the manufacturers, and disclaim responsibility for their accuracy.</p>	<p>64. The Relator’s investigation has determined that drug manufacturers, including the DEFENDANTS, provide First DataBank, Medical Economics and Medi-Span with the specific prices and costs of their drugs and instructions, if necessary, expressed in a manner that allows the price reporting companies to establish the necessary pricing information for publication that is utilized by Medicare, Medicaid and others in determining reimbursements for prescription drugs.</p>

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<p>4. Baxter refused to report an accurate WAC. The vast bulk of Baxter's products at issue here are distributed by a class of business called non-charge back wholesalers. Instead, Baxter reported a "list sales price" which bore no relationship to the price charged in the marketplace to the actual wholesalers, but which was an inflated price charged to very few customers that distributed less than one percent of these products.</p>	<p>65. During the relevant time period of this Complaint, a form entitled "New Product Submission Form" has been provided by First DataBank to drug manufacturers to transmit information including their prices to First DataBank. The form permits drug manufacturers to submit prices expressed in terms of Wholesale (Distributor) Price, Direct Price and AWP Price. After causing new products to be added to a national drug data formulary maintained by First DataBank, drug manufacturers, including DEFENDANTS, thereafter provided additional updated price representations such as Wholesale Net Price, Suggested Retail Price, Direct Price and/or AWP Price, Wholesale (Distributor) Price, Wholesale Net Price and WAC were represented to be the same price by the DEFENDANTS.</p>
<p>5. Baxter thus manipulated the AWP, knowing that health care providers who were being reimbursed based on AWP were indifferent to the cost of purchasing the drug, but instead focused on the "spread" - as it is known in the industry - between the cost and the AWP based reimbursement. Because Baxter's spread was larger than competitors, its products were more attractive to these customers, and it could maximize its revenue.</p>	<p>66. During the relevant time period of this Complaint, forms entitled "Product Listing Verification" and "New Product Information Form" have been provided by Medical Economics/Red Book to drug manufacturers to transmit information including their prices to Medical Economics/Red Book. The forms permit drug manufacturers to submit prices expressed in terms that include, but are not necessarily limited to, AWP. Drug manufacturers, including DEFENDANTS, provide updated price and cost representations to Medical Economics Red Book expressed in terms that include, but are not necessarily limited to, AWP.</p>

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<p>6. States rely upon FDB's published AWP to reimburse providers, and assume that the published AWP is a reasonable indicator of the price paid for the drug. However, because Baxter falsely reported WAC to inflate the AWP and the spread, Baxter deceived the government, which then overpaid for the biologics at issue here.</p>	<p>67. Each of the DEFENDANTS has been the source of the price and cost information reported by First DataBank, Medical Economics and MediSpan to the Medicare and States' Medicaid Programs at all times at issue in this action. The Relator reported its information to the Government, including specific identification of representatives of First DataBank and Medical Economics to whom such information was reported. Thereafter, the Government conducted an investigation which confirmed the information supplied by the Relator including the information that each of the DEFENDANTS has repeatedly and systemically communicated with First DataBank, Medicaid Economics and Medi-Span with the express purpose and effect of causing First DataBank, Medical Economics and Medi-Span to report prices and costs of the specified drugs in amounts set by the DEFENDANTS.</p>
<p>31. Although the charge-back wholesalers purchased less than 1% of the biologics, Baxter reported to FDB that the high prices charged to this tiny market segment was its WAC. Baxter did this with the knowledge that FDB, would, in turn, use this information to calculate AWP, which would then be reported to state and federal health care programs described herein. Since the price charged to less than 1% of its market did not affect sales, Baxter could use it to manipulate the reimbursement system since the published AWP had no correlation to the price charged to the wholesalers that distributed nearly all of Baxter's biologics.</p>	<p>133. <u>Defendants Create the False Price Spread to Induce Sales of Drugs Used to Treat Very Serious Medical Conditions.</u> The attached Exhibit 2 lists some of the DEFENDANTS' drugs and their approved FDA indications as published in the 1998 edition of <i>Drug Facts and Comparisons</i>. The percent of pricing fraud is represented by the mark-up between the DEFENDANTS' AWP listing of the 1998 <i>Drug Topics</i> Red Book and Ven-A-Care's true 1998 wholesale cost for a common size.</p> <p>(See below for the pertinent portion of Exhibit 2 which explicitly presents the Recombinate spread %.)</p>

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37. In the case of Medicaid reimbursement, at 85% of AWP, or \$1.381 per unit, the difference between that and the actual acquisition cost of \$0.89 is \$0.491. The nearly 50-cent per unit spread is also gross margin for the provider.	
	162. Notwithstanding the DEFENDANTS' knowledge that the Government relied upon the DEFENDANTS' representations of price and cost and their knowledge of the applicable statutory requirements and prohibitions, each of the DEFENDANTS repeatedly, systematically and falsely reported inflated price and cost information, including but not limited to:
	b) Defendants ABBOTT, [REDACTED] BAXTER, BRISTOL-MYERS, [REDACTED] repeatedly, systematically and falsely represented to the Medicare and States' Medicaid Programs that the prices of certain of their specified drugs were increasing or remaining substantially constant when they knew that in truth and in fact the prices had fallen substantially or were otherwise priced far below the represented prices and the Medicare and States' Medicaid Programs would pay and approve claims based on their false representations of the price of their drugs.

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	<p>177. Throughout the period starting from on or before December 31, 1993 and continuing throughout the present date, Defendant BAXTER knowingly caused Medicare/Medicaid to pay false or fraudulent claims for prescription drugs and biologicals (collectively referred to in this Section as the “drugs”), including those specified in this Section, and further made or used false or fraudulent records and/or statements to get such claims paid or approved. As a result of the said actions of Defendant BAXTER and those persons and entities acting directly or indirectly in concert with Defendant BAXTER, Medicare/Medicaid paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs, including those specified in this Section. The acts committed by Defendant BAXTER that caused Medicare/Medicaid to pay or approve said false or fraudulent claims included, but were not necessarily limited to, knowingly making false or fraudulent representations about prices and costs of the drugs, including those specified in this Section which Defendant BAXTER knew would be utilized by Medicare/Medicaid in paying or approving claims for such drugs and using the Spread as a financial inducement to increase sales of the Defendant’s drugs. Each of said representations was in fact utilized by Medicare/Medicaid in paying or approving claims for the drugs, including those specified in this Section.</p>

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	<p>178. Defendant BAXTER knowingly caused its false or fraudulent price and cost representations to be published in the years specified in this Section in the Red Book, Blue Book and the First DataBank's Automated Services and Medi-Span and further made or used false records or statements regarding its prices and costs of the drugs, including those specified in this Section and submitted same to the Medicare/Medicaid continuously throughout the years specified in this Section. By way of example, the said false price and cost representations as they were reported by Defendant BAXTER and reflected in Red Book, Blue Book, First DataBank and the inflated Medicaid reimbursement amounts calculated by Florida and Texas have been organized into a chart form for certain of the drugs in question. Amounts contained in the Florida Medicaid reimbursement column reflect the falsely inflated reported First DataBank WAC costs because Florida's reimbursement methodology for the years listed in each chart was WAC (as reported in First DataBank) plus 7%. Amounts contained in the Texas WEAC (Wholesale Estimated Acquisition Cost) reimbursement column also reflect the fact that the Defendant's price and cost representations were falsely inflated as explained more fully in paragraph 110, herein. The amount listed under the Relator's Cost column reflects the actual prices that were available to the Relator for the listed drugs from BAXTER or a wholesaler. As a very small infusion pharmacy, the Relator did not always receive the lowest prices available to volume purchasers. As a very small infusion pharmacy, the Relator did not always receive the lowest prices available to volume purchasers. Accordingly, in many instances the actual cost to Providers for the drug was significantly lower than that paid by the Relator.</p>

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	In instances where a Provider did pay less, the Spread on said drugs would have been correspondingly greater than that received by the Relator. A listing of drugs with respect to which BAXTER knowingly caused Medicare/Medicaid to pay falsely inflated reimbursement amounts by reporting falsely inflated drug costs and prices is contained in Exhibit 6 attached hereto.
	149. The DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that their conduct would cause Medicare/Medicaid to pay claims for the specified drugs in amounts exceeding that contemplated by applicable law, in part, because:
	(a) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that Medicaid was required to pay claims based upon the drugs' Estimated Acquisition Cost ("EAC") to the Provider submitting the claim. 42 C.F.R. 447.331.
	(b) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that federal statutes and regulations limited payment of Medicaid claims for the specified drugs to a reasonable estimation of the acquisition cost.
	(c) Each of the DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that federal statutes and regulations limit payment of Medicare Part B claims for the specified drugs to 80% of a reasonable cost, one that reflects the true cost of the drug. See 42 C.F.R. 405.517.

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	(d) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that neither Medicare nor Medicaid was authorized or permitted by applicable law to pay claims for the specified drugs in excessive amounts.
	(e) Each DEFENDANT DRUG MANUFACTURER knew or recklessly disregarded or acted in deliberate ignorance of the fact that the State Medicaid Programs contracted through their fiscal agents with First Databank and Medi-Span to obtain the DEFENDANT's reported prices and costs and used the prices from First DataBank and Medi-Span to establish the estimated acquisition cost for the specified drugs for reimbursement purposes.
	(f) Each DEFENDANT knew or recklessly disregarded or acted in deliberate ignorance of the fact that Medicare, through its Carriers and DMERCs, utilized DEFENDANTS' reported AWP prices as contained in Red Book, to establish its reimbursement amounts for the specified drugs.
	(g) Each of the DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that the State Medicaid Programs utilized DEFENDANT'S reported prices and costs to calculate the Estimated Acquisition Cost.
	(h) Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that they were supplying to First DataBank, Red Book and Medi-Span, prices and costs which these reporting compendia reported to Medicare and/or Medicaid and that these compendia relied solely on DEFENDANTS to obtain its prices.

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	(i) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that the required wholesalers to report back to DEFENDANTS, and the wholesalers did in fact routinely report back to the DEFENDANTS, all prescription drug sales by NDC number, provider name and the actual price the Provider had paid.
	(j) Each of the DEFENDANTS knew, and in fact, closely monitored the prices, with and without discounts, that Providers as well as wholesalers were paying for DEFENDANTS' specified drugs. Such information was of utmost importance to DEFENDANTS in conducting their business affairs such as calculating and projecting revenue and profits, and making marketing, manufacturing and distribution decisions.
	(k) Each of the DEFENDANTS had information readily available to them which would have enabled them to report price and cost information which fairly and reasonably represented sales in the marketplace.
	(l) Each of the DEFENDANTS was, at a minimum, generally aware of the size of the "Spread" for their respective specified drugs under both Medicare and Medicaid.
	(m) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that the prices they reported to First DataBank, Red Book and Medi-Span were vastly higher than, and bore no relation whatsoever to, the actual prices which Providers were paying for their specified drugs.

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	(n) The DEFENDANTS knew or recklessly disregarded or acted in deliberate ignorance of the fact that, all other factors being equal, the greater the "Spread" on a drug, the greater the likelihood a Provider would purchase that drug versus a competing brand or generic drug.
	(o) Each of the DEFENDANTS systematically concealed or otherwise failed to report decreases in the actual prices to the Providers of the specified drugs.
	150. Each of the DEFENDANT DRUG MANUFACTURERS knew or recklessly disregarded or acted in deliberate ignorance of the fact that Federal and State statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations.
	161. . . . For several years, various Governmental agencies including the HHS Office of Inspector General "OIG" and the General Accounting Office "GAO" attempted to examine the issue of the reasonableness of reimbursements by the Medicare and States' Medicaid Programs for many of the drugs at issue in this Fourth Amended Complaint. The OIG's and GAO's efforts were thwarted, in part, by the DEFENDANTS withholding and concealing pertinent information that was being sought by the OIG and GAO. The OIG and GAO attempted through numerous published reports to identify the problem of unreasonable reimbursements; however, they were unsuccessful due to the actions of the DEFENDANTS. The DEFENDANTS concealed and disguised the unreasonable reimbursements from the United States Government and States' Medicaid Programs, in part, by the following facts and circumstances:

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	a) The DEFENDANTS can and do make truthful representations of price and costs for many of their drugs sold in retail community pharmacies and, in some instances, infusion, injectable and inhalation drugs and biologicals sold to physician groups, outpatient clinics and pharmacies.
	b) Some of the DEFENDANTS make representations of cost and price in terms of "List Price," "Wholesale Net," Direct Price "DP" or "DIRP," or Wholesaler Acquisition Costs, "WAC," to which Medical Economics and First DataBank apply an industry average mark-up and establish an AWP
	c) Some of the DEFENDANTS make representations of cost and price in terms of both AWP and DP (or DIRP).
	d) All of the DEFENDANTS make or cause to be made falsely inflated price and cost representations of one or more of Wholesale Net Price/WAC, Direct Price and/or AWP that were utilized by the government in calculating and paying drug reimbursements.

Chart from page 138 of the Ven-a-Care Second Amended Complaint originally filed under seal on August 13, 1997, Case No. 95-1354-Civ-Marcus, Southern District of Florida, redacted copy filed in severed Baxter action, Case No. 10-21745-Civ-Gold, Southern District of Florida, Doc. 5-1, FLSD Docket 6/4/10.

g. BIOLOGICAL: FACTOR VIII
(Antihemophilic Factor (recombinant)), per I.U.
Recombinate 250 I.U.

MEDICAID
NDC NO.: 00944-2938-01

MEDICARE
HCPCS J1561

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993		\$1.18					
1994		\$1.18		\$1.18			
1995		\$1.18		\$1.18			
1996		\$1.18		\$1.18			\$0.78
1997		\$1.18					\$0.78

Partial Chart from page 6, Exhibit 2 of the Ven-a-Care Fourth Amended Complaint filed 12/11/02 (Docket Entry # 8205-3):

BAXTER		
<u>DRUG</u>	<u>F.D.A. APPROVED INDICATIONS</u>	<u>THE FALSE PRICE SPREAD</u>
<u>Hemofil M</u> <u>(Antihemophilic factor,</u> <u>human, monoclonal)</u>	<u>Classical Hemophilia</u> <u>(Hemophilia A)</u>	<u>46%</u>
<u>Recombinate</u> <u>(Antihemophilic factor,</u> <u>recombinant)</u>	<u>Classical Hemophilia</u> <u>(Hemophilia A)</u>	<u>41%</u>